

Improving coverage of birth-dose vaccination for hepatitis B, making links between vaccine delivery and postnatal care for maternal and newborn survival

This is the story of how the Burnet Institute, as a member of the Women's and Children's Health Knowledge Hub (WCH Knowledge Hub), undertook a review of evidence, policy, practice and implementation of birth-dose vaccination for hepatitis B between 2010-2012. The review resulted in two major documents: the development of a World Health Organization (WHO) monograph on evidence and best practice to increase coverage of the hepatitis B birth-dose vaccine, and guidelines for health managers to increase coverage of hepatitis B birth dose. This is the first time that any organisation has undertaken a comprehensive global review in this area. Importantly, it represents a departure from other vaccine evidence reviews as it provides strategies for increasing coverage in both health centres and in home birth settings. In both settings, the guidelines for health managers use the timely delivery of the hepatitis B birth dose to improve coordination between maternal, neonatal and immunisation health services in the first 24 hours after childbirth, a critical period when 60% of maternal deaths occur.

The Challenge

Globally, over 2 billion people carry the hepatitis B virus (HBV), with 350 million of those having chronic infection with the risk of life-threatening liver disease. Annually, between 500,000-700,000 people die as a result of diseases stemming from HBV. Vaccines for hepatitis B have existed since 1982. In 1992, the hepatitis B vaccine was adopted as the seventh universal vaccine by the World Health Organization's Expanded Program on Immunisations. At that time the program endorsed a target of universal hepatitis B immunization by 1997.

Despite this, chronic hepatitis B infection remains a global health problem. Many HBV infections are acquired early in life; in areas where the virus is highly prevalent, mother to child transmission at the time of birth is the most common form of infection. Evidence suggests that a hepatitis B birth dose vaccine, administered to a child within the first 24 hours of life, reduces the likelihood of the child being infected by the HBV by 80%.

While a birth-dose vaccine for hepatitis B exists, only about a quarter of newborns worldwide receive it. Successfully delivering these vaccines to newborns within 24 hours is not easy for a number of reasons, spanning poor funding for the provision of monovalent hepatitis B birth dose, varying national policy frameworks regarding vaccines, difficulty accessing neonates, poor coordination between maternal and neonatal staff, and cold chain challenges. What was lacking was an analysis of existing evidence on hepatitis B birth dose coverage in the context of current health policy and practice frameworks. As Dr Robin Biellik, member of the hepatitis B working group of the WHO's Immunization Practices Advisory Committee, states, 'hepatitis B birth dose was on the Committee's agenda, along with 20 other items, but further evidence was needed.'



The BD Uniject injection system, developed by PATH, licensed to BD. Photo: PATH/Patrick McKern.

Action

As a response to many of these challenges the Burnet Institute was tasked by the WHO to research policy and implementation guidelines to create an evidence base on increasing coverage of the birth dose vaccine. While the WHO monograph was the final product of this research, it was not the only one. The monograph is the result of reviews, consultations, and opportunistic funding. These events then influenced the development of policy in a timely fashion. In this sense, the factors that led to the development of the monograph had a snowball effect; the effect of each action was enhanced by factors such as flexible funding, timing, and active networks. The timeline below provides a schedule of events that helped to create a positive environment for this initiative, including:

Timeline

- 2008 Staff in the Centre for International Health at the Burnet Institute begin a trial to test community provision of hepatitis B birth dose linked to postnatal care, in Papua New Guinea (PNG). The trial uses Uniject™, a pre-filled auto-disable injection device that is easier to use than standard needles and syringes.
- 2009 Under the WCH Knowledge Hub initiative, Burnet begins an analysis of community-based care for maternal and child health in four countries: PNG, Solomon Islands, Indonesia and Lao PDR. This study includes the expertise of people working on the PNG hepatitis B birth dose project in an advisor capacity.
- 2010
- March: Under the WCH Knowledge Hub, Burnet's review on community-based care for maternal and child health identifies that better access to skilled childbirth care and the integration of vaccination with maternal and newborn care, may significantly improve coverage within the first 24 hours.
- June: The WHO's new global hepatitis program and its Immunization Practices Advisory Committee discusses issues around increased coverage of the hepatitis B birth dose vaccine. Based on the combination of Burnet's PNG health worker and Uniject™ project, and the WCH Knowledge Hub funded community care analysis, the WHO provides seed funding to undertake a background review and technical consultation to document global evidence and best practice.
- August: The Burnet project in PNG shows significant improvement in birth-dose coverage at both the health centre level (approximately 50% higher) and for home births (approximately 70% higher).
- Funded partly by the WHO and partly by the WCH Knowledge Hub, a literature review, led by Burnet, is conducted with the Victorian Infectious Diseases Reference Laboratory into evidence around delivery of hepatitis B birth dose.
- December: This review forms the evidence base for discussions at a WHO Technical Consultation on hepatitis B birth dose held in Melbourne, Australia. Jointly funded by the WHO and the WCH Knowledge Hub, and led by the Burnet Institute, the consultation includes representatives from the Immunization Practices Advisory Committee, the Western Pacific Regional Office of the WHO, the Victorian Infectious Diseases Reference Laboratory, the USA Centres for Disease Control and Prevention, the National Department of Health PNG, Hepatitis Australia, and the Australasian Society for HIV Medicine. One result is the 'Melbourne Statement on Prevention of Perinatal Transmission of Hepatitis B Virus: A Call for the Consideration of All Available Strategies', signed and endorsed by all 19 participants of the technical consultation.
- 2011
- April: The Immunization Practices Advisory Committee acknowledges the importance of the 'Melbourne Statement', and requests a more rigorous review of global evidence, to form a base for guidance materials for increased coverage of hepatitis B birth-dose. WCH Knowledge Hub resources are applied to this, in part to ensure proper linkage with other postnatal care.
- May: Reference to the 'Melbourne Statement' appears in the WHO *Weekly Epidemiological Record*.
- 2012
- A systematically performed scoping review, as requested by the Immunisation Practices Advisory Committee in April 2011, is completed by the Burnet Institute, and is endorsed for publication as a WHO monograph. Work begins on a WHO global guidance document, 'Manual for hepatitis B birth dose implementation', led by USA Centres for Disease Control and Prevention (CDC). Burnet Institute, for the WCH Knowledge Hub, have drafted several chapters.

Results

At the global policy and implementation level, the final result of this initiative is the WHO Monograph on practices to improve coverage of the hepatitis B birth dose vaccine and the CDC / WHO global manual. At the policy and practice level, the evidence around health workers using Uniject™ to deliver birth dose, and the steps to integrate vaccinations with maternal and newborn care have been included in new 'task shifting' guidelines published by the Reproductive Health Research division of the WHO. In order to disseminate to a wide audience, a policy brief was prepared and distributed to a wide audience. It received over 300 readers on the WCH Knowledge Hub website, and an article by Burnet on the same research received over 1000 readers on *the Conversation*.

While the monograph provides a convenient and authoritative compilation of best practice, the manual and task-shifting guidelines provide a toolkit for health program managers for the implementation of birth-dose vaccination. At the regional level the initial scoping review (that led to the publication of the monograph) has fed into strategic planning to increase coverage of birth dose undertaken by WHO regional offices in South-East Asia and Africa, both regions that can learn from the Western Pacific region's leadership in birth-dose vaccination and hepatitis B control more generally.

Critically, this is the first time a global WHO immunisation document has included both facility-based and community maternal and neonatal health services as part of the strategy to increase coverage, which increases its potential for sustainability as the strategies utilise existing workers, rather than creating parallel immunisation programs. It also makes strong links to postnatal care in both settings, and advocates for immunisation programs as a lever to improve coverage of other maternal and neonatal interventions in high mortality settings. This also serves the purpose of focussing donor attention to the birth-dose initiative as it provides practical, measurable and fundable interventions.

Conclusion

The reasons this initiative succeeded are multifaceted and concordant with the factors that influence successful translation of evidence to policy.

The timeliness of this activity catalysed its uptake in various circles. Hepatitis B birth dose was at the point of receiving greater attention from bodies like the WHO, but the evidence base for increased coverage was fragmented. The Burnet Institute was able to fill that evidence gap by building on its existing academic and project work. Additionally, similar goals were held by a number of people. Discussions with advocates and policy makers indicated that all were keen to see tangible results from the Melbourne technical consultation. As Edward Reis of the Australasian Society for HIV Medicine stated, 'participants were agreed that the Statement would serve more than one purpose; firstly it would seek to capitalise on the WHO's global hepatitis initiative, secondly it would serve to focus attention on the topic here in Australia and in our region; thirdly, it would serve as a lobbying and advocacy mechanism.'

The project had a logical home at the Burnet Institute. The Institute had its own expertise in the area, having undertaken its own work on hepatitis B birth dose through the Centre for International Health, and an analysis of community-based maternal and child health through the WCH Knowledge Hub. The project was clearly taken forward by individual experts, in particular Dr Chris Morgan, who brought his experience and expertise from both these projects.

The development of the project also benefitted from pre-existing relationships between the Burnet Institute, the Victorian Infectious Diseases Reference Laboratory, and the Australasian Society for HIV Medicine. Burnet was also frequently in touch with the World Health Organization's Western Pacific Regional Office regarding increasing hepatitis B birth-dose coverage in Western Pacific countries. In essence there was a group of people linked through a common interest to increase hepatitis B birth-dose coverage in the Western Pacific, which formed the basis for links with the global network on this issue.

That a global policy document was generated from the technical review is testament to the success of iterative growth in the policy environment. Facilitating this development was a flexible funding model, enabled by the Knowledge Hubs' support, which allowed convening activities to be enhanced for greater impact. For example, the Melbourne technical consultation was able to invite Burnet's existing stakeholders such as PNG Department of Health and the Australasian Society for HIV Medicine, because of WCH Knowledge Hub funding. This engagement with service delivery and health worker representatives made discussions more holistic, less academic, and ultimately resulted in guidelines being more practical and realistic. As Dr Ben Cowie of the Victorian Infectious Diseases Reference Laboratory states, 'the discussions about the potential utility of incorporating maternal and child health services evolved during discussions at the Melbourne Technical Consultation, where a range of practitioners, policy makers, service providers and advocacy organisations were present.' Taken in combination, these were the key strengths of the activity – building on existing knowledge, evidence and networks, with a flexible funding model, to create new initiatives.

Next Steps

The Burnet Institute is writing four chapters for the WHO's global manual on birth-dose vaccination, which is due to be presented for review in mid 2013; a session on hepatitis B birth dose will be included in the 2014 International AIDS Conference being held in Melbourne; and a paper is being prepared for submission in a peer reviewed journal.

The relationships that have been built throughout this process will ensure that birth dose remains on the agenda: Dr Chris Morgan is now a member of the Immunization Practices Advisory Committee; the Australasian Society for HIV Medicine will promulgate the results of the birth-dose guidelines as part of its advocacy work in the Asia Pacific and use the guidelines to seek funding for pilots with regional partners. The Victorian Infectious Diseases Reference Laboratory has used the results of the review to increase collaborations with the immunisation focal point at the Western Pacific Regional Office of the World Health Organization.

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Resources

Practices to improve coverage of the hepatitis B birth-dose vaccine, WHO Monograph, 2012.

Protection against hepatitis B starts at birth, WCH Hub Policy Brief, October 2012.

Guidelines on the Hepatitis B birth dose: Guidance Tools for Health Managers, under preparation by CDC and Burnet Institute for WHO IVB/EPI.

Notes

- 1 The Guidelines were requested by the WHO and created in conjunction with the USA Centre for Disease Control.
- 2 WHO: Prevention and Control of Viral Hepatitis Infection: Framework for Global Action, 2012.
- 3 Muraskin, William, The War Against Hepatitis B: A History of the International Task Force on Hepatitis B Immunization, University of Pennsylvania Press, Philadelphia, 1995, p.216. The standard regime for infant Hepatitis B vaccination dictated immunisations at 2, 4, and 6 months.
- 4 WPRO: Preventing Mother to Child Transmission of Hepatitis B: Operational Field Guidelines of the Delivery of Hepatitis B Birth Dose Vaccine, 2006, p.4.
- 5 WHO: Prevention and Control of Viral Hepatitis Infection: Framework for Global Action, 2012.
- 6 The cold chain describes the conditions under which vaccines must be stored in order to remain effective.
- 7 Skype interview with Dr. Robin Biellik, Hepatitis B working group, Immunization Practices Advisory Committee, 1/11/12. The Committee is tasked with advising the Department of Immunisation, Vaccines, and Biologicals within the World Health Organisation on best practices, guidelines and tools in so that the Global Vaccine Action Plan can be delivered effectively at country level.
- 8 The trial took place in PNG, which is in the Western Pacific Region of the World Health Organization (WHO). This project was undertaken in partnership with Save the Children PNG, the National Department of Health, and Catholic Health Services. Funding came from WHO, UNICEF, AusAID and community donations.
- 9 Optimize Maternal and Newborn Health: <http://www.optimize-mnh.org/>
- 10 The Conversation is an online forum for news and opinion, sourced from the academic and research community.
- 11 Interview with Levinia Crooks, CEO, ASHM, 30/10/12; Interview with Robin Biellik, IPAC, 1/11/12.
- 12 Written response from Mr. Edward Reis, ASHM, 10/11/12
- 13 Phone interview with Dr. Ben Cowie, VIDRL, Interviewed 2/11/12.
- 14 Phone interview with Dr. Levinia Crooks, CEO ASHM, 30/10/12
- 15 Written response from Mr. Edward Reis, ASHM, 10/11/12
- 16 Phone interview with Dr. Ben Cowie, VIDRL, Interviewed 2/11/12

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Compass: Women's and Children's Health Knowledge Hub is a partnership between the Burnet Institute, Menzies School of Health Research and the Centre for International Child Health, University of Melbourne. The Knowledge Hubs for Health are an Australian Agency for International Development (AusAID) initiative that aims to build knowledge, evidence and expertise and inform health policy dialogue relevant to Asia and the Pacific.

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